

## SUBCHAPTER A—GENERAL PROVISIONS

### PART 400—INTRODUCTION; DEFINITIONS

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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh) and 44 U.S.C. Chapter 35.

#### Subpart A—[Reserved]

#### Subpart B—Definitions

##### § 400.200 General definitions.

In this chapter, unless the context indicates otherwise—

*Act* means the Social Security Act, and titles referred to are titles of that Act.

*Administrator* means the Administrator, Health Care Financing Administration.

*ALJ* stands for administrative law judge.

*Area* means the geographical area within the boundaries of a State, or a State or other jurisdiction, designated as constituting an area with respect to which a Professional Standards Review Organization or a Utilization and Quality Control Peer Review Organization has been or may be designated.

*CMP* stands for competitive medical plan.

*Conditions of participation* includes *requirements for participation* as the latter term is used in part 483 of this chapter.

*Condition level deficiencies* includes deficiencies with respect to “level A requirements” as the latter term is used in parts 442 and 483 of this chapter.

*CORF* stands for comprehensive outpatient rehabilitation facility.

*CFR* stands for Code of Federal Regulations.

*CY* stands for calendar year.

*DAB* stands for Departmental Appeals Board.

*Department* means the Department of Health and Human Services (HHS), formerly the Department of Health, Education, and Welfare.

*ESRD* stands for end-stage renal disease.

*FDA* stands for the Food and Drug Administration.

*FQHC* means Federally qualified health center.

*FR* stands for *Federal Register*.

*FY* stands for fiscal year.

*HCFA* stands for Health Care Financing Administration.

*HCPP* stands for health care prepayment plan.

*HHS* stands for the Department of Health and Human Services.

*HHA* stands for home health agency.

*HMO* stands for health maintenance organization.

*ICF* stands for intermediate care facility.

*ICF/MR* stands for intermediate care facility for the mentally retarded.

*Medicaid* means medical assistance provided under a State plan approved under title XIX of the Act.

*Medicare* means the health insurance program for the aged and disabled under title XVIII of the Act.

*NCD* stands for national coverage determination.

*OASDI* stands for the Old Age, Survivors, and Disability Insurance program under title II of the Act.

*OIG* stands for the Department’s Office of the Inspector General.

*Peer review organization* means an organization that has a contract with HCFA, under part B of title XI of the Act, to perform utilization and quality control review of the health care furnished, or to be furnished, to Medicare beneficiaries.

*PRO* stands for peer review organization.

*QDWI* stands for Qualified Disabled and Working Individual.

*QMB* stands for Qualified Medicare Beneficiary.

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*Qualified Disabled and Working Individual* means an individual who—

(1) Is eligible to enroll for Medicare Part A under section 1818A of the Act.

(2) Has income, as determined in accordance with SSI methodologies, that does not exceed 200 percent of the Federal poverty guidelines (as defined and revised annually by the Office of Management and Budget) for a family of the size of the individual's family;

(3) Has resources, as determined in accordance with SSI methodologies, that do not exceed twice the relevant maximum amount established, for SSI eligibility, for an individual or for an individual and his or her spouse; and

(4) Is not otherwise eligible for Medicaid.

*Qualified Medicare Beneficiary* means an individual who—

(1) Is entitled to Medicare Part A, with or without payment of premiums, but is not entitled solely because he or she is eligible to enroll as a QDWI;

(2) Has resources, as determined in accordance with SSI methodologies, that do not exceed twice the maximum amount established for SSI eligibility; and

(3) Has income, as determined in accordance with SSI methodologies, that does not exceed 100 percent of the Federal poverty guidelines.

*Regional Administrator* means a Regional Administrator of HCFA.

*Regional Office* means one of the regional offices of HCFA.

*RHC* stands for rural health clinic.

*RRB* stands for Railroad Retirement Board.

*Secretary* means the Secretary of Health and Human Services.

*SNF* stands for skilled nursing facility.

*Social security benefits* means monthly cash benefits payable under section 202 or 223 of the Act.

*SSA* stands for Social Security Administration.

*United States* means the fifty States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

*U.S.C.* stands for United States Code.

[48 FR 12534, Mar. 25, 1983, as amended at 49 FR 7206, Feb. 27, 1984; 50 FR 15326 and 15358, Apr. 17, 1985; 50 FR 41886, Oct. 16, 1985; 51 FR 43197, Dec. 1, 1986; 52 FR 27764, July 23, 1987; 56 FR 8852, Mar. 1, 1991; 56 FR 38077, Aug. 12, 1991; 57 FR 24975, June 12, 1992; 57 FR 55912, Nov. 25, 1992; 63 FR 35065, June 26, 1998; 63 FR 52611, Oct. 1, 1998; 63 FR 68690, Dec. 14, 1998]

§ 400.202 Definitions specific to Medicare.

As used in connection with the Medicare program, unless the context indicates otherwise—

*Beneficiary* means a person who is entitled to Medicare benefits.

*Carrier* means an entity that has a contract with HCFA to determine and make Medicare payments for Part B benefits payable on a charge basis and to perform other related functions.

*Critical access hospital (CAH)* means a facility designated by HCFA as meeting the applicable requirements of section 1820 of the Act and of subpart F of part 485 of this chapter.

*Entitled* means that an individual meets all the requirements for Medicare benefits.

*Essential access community hospital (EACH)* means a hospital designated by HCFA as meeting the applicable requirements of section 1820 of the Act and of subpart G of part 412 of this chapter, as in effect on September 30, 1997.

*GME* stands for graduate medical education.

*Hospital insurance benefits* means payments on behalf of, and in rare circumstances directly to, an entitled individual for services that are covered under Part A of title XVIII of the Act.

*Intermediary* means an entity that has a contract with HCFA to determine and make Medicare payments for Part A or Part B benefits payable on a cost basis and to perform other related functions.

*Medicare Part A* means the hospital insurance program authorized under Part A of title XVIII of the Act.

*Medicare Part B* means the supplementary medical insurance program authorized under Part B of title XVIII of the Act.

*National coverage determination (NCD)* means a national policy determination

regarding the coverage status of a particular service, that HCFA makes under section 1862(a)(1) of the Act, and publishes as a FEDERAL REGISTER notice or HCFA Ruling. (The term does not include coverage changes mandated by statute.)

*Nonparticipating supplier* means a supplier that does not have an agreement with HCFA to participate in Part B of Medicare in effect on the date of the service.

*Participating supplier* means a supplier that has an agreement with HCFA to participate in Part B of Medicare in effect on the date of the service.

*Payment on an assignment-related basis* means payment for Part B services—

(1) To a physician or other supplier that accepts assignment from the beneficiary, in accordance with § 424.55 or § 424.56 of this chapter;

(2) To a physician or other supplier after the beneficiary's death, in accordance with § 424.64(c)(1) of this chapter; or

(3) To an entity that pays the physician or other supplier under a health benefit plan, in accordance with § 424.66 of this chapter.

*Provider* means a hospital, a CAH, a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, or a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has in effect a similar agreement but only to furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services.

*Railroad retirement benefits* means monthly benefits payable to individuals under the Railroad Retirement Act of 1974 (45 U.S.C. beginning at section 231).

*Services* means medical care or services and items, such as medical diagnosis and treatment, drugs and biologicals, supplies, appliances, and equipment, medical social services, and use of hospital, CAH, or SNF facilities.

*Supplementary medical insurance benefits* means payment to or on behalf of an entitled individual for services cov-

ered under Part B of title XVIII of the Act.

*Supplier* means a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare.

[48 FR 12534, Mar. 25, 1983, as amended at 48 FR 56024, Dec. 16, 1983; 49 FR 3658, Jan. 30, 1984; 51 FR 43197, Dec. 1, 1986; 52 FR 27764, July 23, 1987; 55 FR 24567, June 18, 1990; 56 FR 8852, Mar. 1, 1991; 58 FR 30666, May 26, 1993; 59 FR 6576, Feb. 11, 1994; 60 FR 63175, Dec. 8, 1995; 62 FR 46025, Aug. 29, 1997; 62 FR 59098, Oct. 31, 1997; 63 FR 35065, June 26, 1998]

#### § 400.203 Definitions specific to Medicaid.

As used in connection with the Medicaid program, unless the context indicates otherwise—

*Applicant* means an individual whose written application for Medicaid has been submitted to the agency determining Medicaid eligibility, but has not received final action. This includes an individual (who need not be alive at the time of application) whose application is submitted through a representative or a person acting responsibly for the individual.

*Federal financial participation (FFP)* means the Federal Government's share of a State's expenditures under the Medicaid program.

*FMAP* stands for the Federal medical assistance percentage, which is used to calculate the amount of Federal share of State expenditures for services.

*Medicaid agency* or *agency* means the single State agency administering or supervising the administration of a State Medicaid plan.

*Nursing facility (NF)*, effective October 1, 1990, means an SNF or an ICF participating in the Medicaid program.

*Provider* means any individual or entity furnishing Medicaid services under a provider agreement with the Medicaid agency.

*Recipient* means an individual who has been determined eligible for Medicaid.

*Services* means the types of medical assistance specified in section 1905(a) of the Act and defined in subpart A of part 440 of this chapter.

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*State* means the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa and the Northern Mariana Islands.

*State plan or the plan* means a comprehensive written commitment by a Medicaid agency, submitted under section 1902(a) of the Act, to administer or supervise the administration of a Medicaid program in accordance with Federal requirements.

[48 FR 12534, Mar. 25, 1983, as amended at 50 FR 33029, Aug. 16, 1985; 56 FR 8852, Mar. 1, 1991; 57 FR 29155, June 30, 1992]

**Subpart C—OMB Control Numbers for Approved Collections of Information**

SOURCE: 49 FR 4477, Feb. 7, 1984, unless otherwise noted.

**§ 400.300 Scope.**

This subpart collects and displays control numbers assigned by the Office of Management and Budget (OMB) to collections of information contained in HCFA regulations, in accordance with OMB's regulations for controlling paperwork burdens on the public, 5 CFR part 1320. HCFA intends that the subpart comply with the requirements of section 3507(f) of the Paperwork Reduction Act of 1980, 44 U.S.C. chapter 35 which requires that agencies shall not engage in a "collection of information" without obtaining a control number from OMB.

**§ 400.310 Display of currently valid OMB control numbers.**

Sections in 42 CFR that contain collections of information	Current OMB control Nos.
403.510 .....	0938—0641
405.509 .....	0938—0666
405.512 .....	0938—0008
405.2112, 405.2123, 405.2134, 405.2136–405.2140, 405.2171 .....	0938—0386
409.43 .....	0938—0365
410.105 .....	0938—0267
411.25, 411.32 .....	0938—0564
411.54 .....	0938—0558
411.165 .....	0938—0564
411.404, 411.406 .....	0938—0465
411.408 .....	0938—0566
412.42 .....	0938—0666
412.92 .....	0938—0477
412.105 .....	0938—0456
412.230, 412.232, 412.234, 412.236, 412.254, 412.260, 412.266, 412.278 .....	0938—0573
415.60 .....	0938—0301

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Sections in 42 CFR that contain collections of information	Current OMB control Nos.
415.162 .....	0938—0301
416.43 .....	0938—0506
416.47 .....	0938—0266
and	
0938—0506	
0938—0472	
0938—0610	
417.126 .....	
417.436, 417.801 .....	
418.22, 418.24, 418.28, 418.56, 418.58, 418.70, 418.74 .....	0938—0302
418.30, 418.82, 418.83, 418.96, 418.100 .....	0938—0475
418.96, 418.100 .....	0938—0302
421.117 .....	0938—0542
424.3 .....	0938—0008
424.5, 424.7, 424.20 .....	0938—0454
424.22 .....	0938—0489
424.32, 424.34 .....	0938—0008
431.17 .....	0938—0467
431.50, 431.52, 431.55 .....	0938—0247
431.107 .....	0938—0610
431.306 .....	0938—0467
431.625 .....	0938—0247
431.630 .....	0938—0445
431.800 .....	0938—0247
431.806, 431.830, 431.432, 431.834, 431.836	0938—0438
432.50 .....	0938—0459
433.36, 433.37 .....	0938—0247
433.68, 433.74 .....	0938—0618
433.110, 433.112–433.114, 433.116, 433.117, 433.119–433.121, 433.123, 433.127, 433.130, 433.131, 433.135 .....	0938—0247
433.138 .....	0938—0502
	0938—0553
and	
0938—0555	
0938—0459	
0938—0554	
and	
0938—0555	
0938—0572	
0938—0610	
433.139 .....	
434.27 .....	
434.28 .....	
435.1, 435.910, 435.919, 435.920, 435.940, 435.945, 435.948, 435.952, 435.953, 435.955, 435.960, 435.965, 435.1003, 441.11, 441.15, 441.20 .....	0938—0247
441.56, 441.58, 441.60, 441.61 .....	0938—0354
441.302 .....	0938—0449
441.303 .....	0938—0272
and	
0938—0449	
0938—0613	
0938—0366	
447.31 .....	0938—0287
447.45, 447.50, 447.51, 447.52 .....	0938—0247
447.53 .....	0938—0429
447.55 .....	0938—0247
447.253 .....	0938—0366
	0938—0523
and	
0938—0556	
0938—0193	
0938—0618	
447.272, 447.299 .....	0938—0247
447.302, 447.331, 447.332, 447.333 .....	0938—0247
456.80 .....	0938—0247
456.654 .....	0938—0445
456.700, 456.705, 456.709, 456.711, 456.712	0938—0659
462.102, 462.103 .....	0938—0526
466.70, 466.72, 466.74 .....	0938—0445
466.78 .....	0938—0445
and	
0938—0665	
0938—0445	
0938—0443	
0938—0426	
466.80, 466.94 .....	
473.18, 473.34, 473.36, 473.42 .....	
476.104, 476.105, 476.116, 476.134 .....	

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Sections in 42 CFR that contain collections of information	Current OMB control Nos.
481.61 .....	0938—0328
482.12, 482.21, 482.22, 482.27, 482.30, 482.41, 482.43, 482.53, 482.56, 482.57, 482.60, 482.62 .....	0938—0328
483.10 .....	0938—0610
483.410, 483.420, 483.440, 483.460, 483.470	0938—0366
484.1, 484.2 .....	0938—0365
484.10 .....	0938—0365 and 0938—0610
484.12, 484.14, 484.16, 484.18, 484.30, 484.32, 484.34, 484.36, 484.48, 484.52 .....	0938—0365
485.56, 485.58, 485.60, 485.64, 485.66 .....	0938—0267 and 0938—0538
485.709, 485.711, 485.717, 485.719, 485.721, 487.723, 485.725, 485.727 .....	0938—0336
486.104, 486.106, 486.110 .....	0938—0338
486.155, 486.161, 486.163 .....	0938—0336
488.10 .....	0938—0646
488.18 .....	0938—0667
488.26 .....	0938—0646
489.20 .....	0938—0564 and 0938—0667
489.24 .....	0938—0334 0938—0663 and 0938—0667
489.102 .....	0938—0610
491.9, 491.10 .....	0938—0334
493.35, 493.37, 493.39, 493.43, 493.45, 493.47, 493.49, 493.51, 493.53, 493.55, 493.60, 493.61, 493.62, 493.63 .....	0938—0612
493.614, 493.633, 494.634 .....	0938—0607
493.801—493.1285, 493.1425, 493.1701, 493.1703, 493.1705, 493.1707, 493.1709, 493.1711, 493.1713, 493.1715, 493.1717, 493.1719, 493.1721, 493.1775, 493.1776, 493.1777, 493.1780, 493.2001 .....	0938—0612
494.52, 494.54, 494.56, 494.58, 494.64 .....	0938—0608
498.22, 498.40, 498.58, 498.82 .....	0938—0508
1004.40, 1004.50, 1004.60, 1004.70 .....	0938—0444

[60 FR 50445, Sept. 29, 1995, as amended at 60 FR 63188, Dec. 8, 1995]

**PART 401—GENERAL ADMINISTRATIVE REQUIREMENTS**

**Subpart A—[Reserved]**

**Subpart B—Confidentiality and Disclosure**

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- 401.133 Availability of official reports on providers and suppliers of services, State agencies, intermediaries, and carriers under Medicare.
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- 401.136 Requests for information or records.
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**Subparts C—E—[Reserved]**

**Subpart F—Claims Collection and Compromise**

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- 401.605 Omissions not a defense.
- 401.607 Claims collection.
- 401.613 Compromise of claims.
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- 401.621 Termination of collection action.
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AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh). Subpart F is also issued under the authority of the Federal Claims Collection Act (31 U.S.C. 3711).

**Subpart A—[Reserved]**

**Subpart B—Confidentiality and Disclosure**

SOURCE: 46 FR 55696, Nov. 12, 1981, unless otherwise noted.

**§ 401.101 Purpose and scope.**

- (a) The regulations in this subpart:
  - (1) Implement section 1106(a) of the Social Security Act as it applies to the Health Care Financing Administration (HCFA). The rules apply to information obtained by officers or employees of HCFA in the course of administering title XVIII of the Social Security Act (Medicare), information obtained by Medicare intermediaries or carriers in the course of carrying out agreements